

REMARKS

Upon entry of the above amendments, this application will contain claims 1-29 pending and under consideration. In this present Response, claims 6 and 11 have been amended.

For the reasons discussed more fully below, it is believed that the claimed invention is patentably distinct from the cited references. Withdrawal of all rejections and allowance of this application is respectfully requested.

Claim Rejections Under 35 USC §103

Claims 1-29 were rejected under 35 USC §103(a) over Wironen et al. (US 2002/0076429).

The Applicants respectfully traverse the Examiner's rejection. The claimed invention recites that the composition includes osteogenic factor and at least 20% by volume of a porous particulate mineral, as well as, the resorbable paste. The Applicants have determined a result effective parameter that has not been previously known or discussed in the references. Specifically, the Applicants have determined that incorporation of effective inductive amounts of osteogenic factors such as bone morphogenic proteins stimulates the osteoclasts such that the resorbable carrier is quickly resorbed and can cause the performance of the composition to suffer to the extent that sporadic bone growth can be observed. (Application, page 12, lines 12-29.) In essence, the osteogenic factors stimulate both osteoblasts that induce bone growth as well as osteoclasts that induce bone absorption. This results in a weakened, incomplete healing or psuedoarthrosis at the defect site.

This observation is further detailed in Example 1 beginning on page 21, line 16. Specifically referring to Figure 2 and the application on page 22, line 18 through page 23, line 6, it is noted that the 0.001 mg of rhBMP-2 and gelatin bone paste samples were more effective at initiating calcification than the 0.002 mg of rhBMP-2 in gelatin bone paste samples. It was also noted that the 21-day samples which included the higher concentration of the rhBMP-2 showed diminished calcification compared to the 14 sample, thus indicating that a higher concentration of the osteogenic factors also stimulates the osteoclastic potentiation leading to enhanced resorption of the collagen matrix.

In response to this observation, the Applicants have determined that incorporating at least 20% by volume of a porous particulate mineral provides an effective scaffold for bone ingrowth

to mitigate the potentiating effect of the osteoclast induction. This observation is a result effective parameter which has not been observed, described, or discussed in the prior art references and, in particular, not disclosed or discussed in the Wironen reference. Therefore, this variable cannot be optimized considering the prior art references. (MPEP §2144.05 II.) Therefore, the Applicants request that the rejections of the claims over Wironen be withdrawn and this application be allowed to issue with claims 1-29.

Claim Amendments

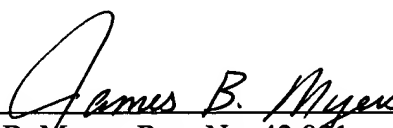
Claims 6 and 11 have been amended to correct minor typographical errors. Claim 6 has been amended to replace "hydroxyapitite" with "hydroxyapatite". Claim 11 has been amended to replace "platlet" with "platelet". It is believed that these amendments do not add any new matter.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the cited references, either singly, or in combination, do not disclose or make obvious the claimed invention. Accordingly, reconsideration leading to withdraw of all the rejections under 35 U.S.C. §103 and passage of this application containing claims 1-29 are respectfully requested. Additionally, the Examiner is invited to telephone the undersigned attorney if there are any questions about this submission or other matters, which may be addressed in that fashion.

Respectfully submitted,

By: _____


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